510(k) Summary **EXHIBIT #1**

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part.807.92.
The assigned 510(K) Number is not applicable.

Date: March , 2009

OCT - 2 2009

## 1. Submitter:

| | |
|---|---|
| Submitted by: | Infopia Co.,ltd.<br>#1603, Dongil Technotown A Bldg.,<br>889-3, Kwanyang2-Dong, Dongan - Gu<br>Anyang, Kyunggi 431-716, Korea<br>Phone +82-31-423-6170<br>Fax +82-31-423-6171 |
| Contact: | Bryan Oh<br>Phone: 1-321-267-9911<br>Fax: 1-321-267-5582 |

## 2. Device:

| | |
|---|---|
| Propriety Name | Eocene™ Glucose Telecommunication system<br>Blood glucose monitoring system |
| Common Name | Data Management system; Accessory to Medical Device |
| Classification Name: | System, test, blood glucose, over the counter<br>Glucose Oxidase<br>Single (specified) analyte controls<br>Physiological signal transmitters and receivers |
| Classification: | Class II<br>21 CFR Part 862.1345,<br>21 CFR Part 862.1660<br>21 CFR Part 870.2910 |
| Product Code: | NBW, [redacted], [redacted] JQP |

## 3. Predicate Device:

GlucoLab™ Blood Glucose Monitoring System(Infopia co., Ltd.)
K051285

## 4. Description:

Data transmitted by the Eocene™ system is available online for you or your designed healthcare professionals to review within the Eocene Secure website. To register your Eocene™ cradle for use with the Eocene systems, contact the dealer you purchased your device from or visit www.eocenesystems.com for more information. For best results, follow the daily testing frequency prescribed by your and upload your data at least once a week or as indicated by your provider.

The Eocene™ system may be used with GlucoLab™ or Eclipse™ Diabetes Monitoring Systems.

## 5. Indications for use:

The GLUCOLAB™ Diabetes Monitoring System and EOCENE™ System is used for the quantitative measurement of glucose level in whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings., including physician's office laboratories and point of care sites . The GLUCOLAB™ System and EOCENE™ System provide plasma equivalent results. The GLUCOLAB™ System and EOCENE™ System is not intended to be used with neonatal blood samples. The GLUCOLAB™ System and EOCENE™ System is for testing outside the body (in vitro diagnostic use only).
Testing sites include the traditional fingertip testing along with alternate site testing on the forearm, upper arm, palm, calf and thigh.

GlucoLab™ control is used with GlucoLab™ Brand System to check that the meter and test strips are working together as a system and that you are performing the test correctly. It is very important that you do control solution tests routinely to make sure you are getting accurate results.

Control Solutions are sold separately.

## 6. Comparison of Technological Characteristics with Predicate:

The GLUCOLAB™ Diabetes Monitoring System still operates under the same technological characteristics as the predicate device cleared under K051285.

This Eocene™ System is used with the GLUCOLAB™ Diabetes Monitoring System. It is composed of the Eocene cradle, DC 5V Adaptor, and phone line.

It allows to use the phone line to upload GlucoLab™ data to a database server. This does not affect to the safety and effectiveness of the GlucoLab data.

## 7. Performance Data:

**Non-clinical**: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the Eocene™ Glucose Telecommunication. Testing involved the verification of software requirement specifications, product requirement specifications and user interface requirement specifications from the risk analysis. The device passed all of the tests based on pre-determined Pass/Fail criteria.

## 8. Conclusion

The data from non clinical tests show that the use of the Eocene™ Glucose Telecommunication system is as safe and effective as the legally marketed predicate device (GlucoLab™).

Therefore we conclude that the Eocene™ Glucose Telecommunication system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Infopia Co., Ltd
c/o Maria F Griffin,
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

OCT - 2 2009

Re: k090712
Trade/Device Name: Eocene System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: Sep 2, 2009
Received: Sep 3, 2009

Dear: Ms. Griffin,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

**EXHIBIT #3**

# Indications for Use



**510(k) Number (if known):** k090712

**Device Name :** GLUCOLAB™ Diabetes Monitoring System and EOCENE™ System

**Indications For Use:**
The GLUCOLAB™ Diabetes Monitoring System and EOCENE™ System is used for the quantitative measurement of glucose level in capillary whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings., including physician's office laboratories and point of care sites . The GLUCOLAB™ System and EOCENE™ System is not to be used for diagnosis, screening of diabetes or for neonatal use. The GLUCOLAB™ System and EOCENE™ System are for testing outside the body (in vitro diagnostic use only).

Testing sites include the traditional fingertip testing along with alternate site testing on the forearm, upper arm, palm, calf and thigh.

GlucoLab™ control is used with GlucoLab™ Brand System to check that the meter and test strips are working together as a system and that you are performing the test correctly

**Prescription Use** __X____ **(Per 21 CFR 801 Subpart D)**

**Over-The Counter Use** ___ X __ **AND/OR (21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)**

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k090712